

PACKAGE LEAFLET

Package leaflet: Information for the user

Nusvelta 4 mg film-coated tablets

drospirenone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> is a contraceptive pill and is used to prevent pregnancy. Each blister of <Invented name> contains 24 white tablets, also called active tablets, and 4 green tablets, also called placebo tablets, that do not contain active substance. The two differently coloured tablets are arranged in order.

Each of the 24 white active tablets contains a small amount of one type of female sex hormone, the progestogen drospirenone. For this reason <Invented name> is called a progestogen-only-pill (POP). Contrary to the combined pills, POPs don't contain any oestrogen hormone next to the progestogen. For this reason, <Invented name> can be used by women who do not tolerate oestrogens.

<Invented name> provides high contraceptive efficacy. The contraceptive effect of <Invented name> is based on the inhibition of ovulation, changes in the cervical mucus and effects on the endometrium, which becomes thinner.

A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of <Invented name>. You also may not have any bleeding at all.

2. What you need to know before you take <Invented name>

Do not take <Invented name>:

- if you are allergic to drospirenone or any of the other ingredients of this medicine (listed in section 6).
- if you have a blood clot in a blood vessel e.g. of the legs (deep venous thrombosis) or of the lungs (pulmonary embolism).
- if you have or have had a liver disease and your liver function is still not normal.
- if your kidneys are not working well (renal failure).
- if you have or are suspected to have a cancer that is sensitive to sex-steroids, such as certain types of breast cancer.
- if you have any unexplained vaginal bleeding.

If any of these conditions appear when using <Invented name>, stop taking this medicine immediately and contact your doctor.

Warnings and precautions

<Invented name> , like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Talk to your doctor before starting to use <Invented name> if any of the following conditions apply to you:

- you have ever had a thrombosis (formation of a blood clot in a blood vessel).
- you have liver cancer, if you have jaundice (yellowing of the skin) or liver disease and your liver is not working normally.
- you have ever had breast cancer.
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly on the face); if this is the case, you will need to avoid exposure to the sun or ultraviolet radiation during treatment with <Invented name> .
- diabetes.
- you have high blood pressure.
- your kidneys are not working well, as your doctor will do a blood test to check potassium levels during the first cycle.

If you suffer a worsening or first appearance of any of these conditions, you should contact your doctor. Your doctor should then decide whether you should stop taking <Invented name> and may advise you to use a non-hormonal method of birth control.

Breast cancer

Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.

Breast cancer has been found slightly more often in women who take the combined Pill than in women of the same age who do not take the combined Pill. If women stop taking the combined Pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the combined Pill.

Breast cancer is rare under 40 years of age. Breast cancers found in women who take the combined Pill, seem less likely to spread than breast cancers found in women who do not take the combined Pill. It is not known whether the difference in breast cancer risk is caused by the combined Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

The risk of breast cancer in users of progestogen-only preparations like <Invented name> is believed to be similar to that in women who use the combined Pill, but the evidence is less conclusive.

Thrombosis (formation of a blood clot in a blood vessel).

See your doctor immediately, if you notice possible signs of a thrombosis (see also ‘Regular check-ups’).

Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called “pulmonary embolism”. As a result, fatal situations may occur.

There may be a slightly increased risk of thrombosis with progestogen-only preparation. The risk of thrombosis is higher if a member of your family (a sibling or a parent) has had thrombosis at an relatively early age, with increasing age, obesity, prolonged immobilization, major surgery or major trauma.

There is no apparent risk of having a heart attack or stroke (a blood clot in the brain) with a progestogen-only preparation. The risk is rather related to increasing age, increase in blood pressure and smoking.

The risk of stroke may be slightly increased in women with high blood pressure when taking progestogen-

only preparations.

Psychiatric disorders:

Some women using hormonal contraceptives including <Invented name> have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Medical examination:

Before you start taking <Invented name> for the first time or if you re-start the treatment after some time of not taking it, your doctor will ask you some questions about your health and will do a complete physical examination, including blood pressure measurements. Your doctor will tell you how often you should go for control visits.

Children and adolescents

<Invented name> is used after menarche (the first menstrual bleeding of a woman).

Other medicines and <Invented name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. They can tell you if you need take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Some medicines:

- can have an influence on the blood levels of <Invented name>
- can make it less effective in preventing pregnancy
- can cause unexpected bleeding.

These include medicines used for the treatment of:

- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, felbamate, topiramate);
- tuberculosis (e.g. rifampicin);
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz);
- Hepatitis C Virus infections (e.g. boceprevir, telaprevir)
- other infections (griseofulvin);
- high blood pressure in the blood vessels in the lungs (bosentan);
- depressive mood (the herbal remedy St. John's wort)
- certain bacterial infections (e.g. clarithromycin, erythromycin)
- fungal infections (e.g. fluconazole, itraconazole, ketoconazole, voriconazole)
- high blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem)

If you are taking medicines in a short-term treatment that might make <Invented name> less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on <Invented name> may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long. If you are taking medicines or herbal products beyond the end of the white active tablets, discard the green placebo tablets and start the next pack right away.

If you are taking medicines in a long-term treatment that might make <Invented name> less effective, your doctor may advise you to use a non-hormonal method of birth control.

<Invented name> may also interfere with how other medicines work e.g:

- ciclosporine used to prevent rejection of transplanted organs (the effect may be increased)
- lamotrigine used for epilepsy (the effect may be decreased)

- certain diuretics (aldosterone antagonists, potassium-sparing diuretics). Your doctor may recommend a blood test to check potassium levels during the first treatment cycle with <Invented name>.

<Invented name> with food and drink

Avoid grapefruit or grapefruit juice while you are taking <Invented name>.

Pregnancy and breast-feeding

Pregnancy

Do not use <Invented name> if you are pregnant, or think you may be pregnant.

Use of <Invented name> prior or during pregnancy has not shown to increase risk of birth defects.

However, undesirable effects cannot be excluded.

Breast-feeding

<Invented name> may be used while you are breast-feeding.

No effects on the breastfed newborns/infants are anticipated. However, very small amounts of drospirenone are excreted in the breast milk

Driving and using machines

No effects on ability to drive and use machines are observed in users of oral hormonal contraceptives, although no studies have been performed with <Invented name>.

<Invented name> contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Regular check-ups

When you are using <Invented name>, your doctor will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible if:

- you have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis);
- you have a sudden, severe stomach ache or look jaundiced (you may notice yellowing of the skin and the whites of the eyes or dark urine, possibly indicating liver problems);
- you feel a lump in your breast (possibly indicating breast cancer);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are pregnant.

3. How to take <Invented name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Each blister of <Invented name> contains 24 white active tablets and 4 green placebo tablets. The two differently coloured tablets are arranged in order.

Take one tablet of <Invented name> every day with a little water if necessary. You may take the tablets with or without food (See section “<Invented name> with food and drink”). You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours.

Do not confuse the tablets: Because of the different composition of the tablets it is necessary to begin with the first white tablet on the upper left and to take the tablets every day. For the correct order, follow the direction of the arrows and the sequence of numbers on the blister .

The first tablet of the treatment should be taken on the first day of menstrual bleeding. Thereafter tablet taking is continuous. Take a white active tablet for the first 24 days and then a green placebo tablet for the last 4 days. You must then start a new pack straightaway without a break in daily tablet intake. There is therefore no gap between two packs.

You may have some bleedings during the use of <Invented name>, or you may also have no bleeding at all, but you must continue to take your tablets as normal without interruption.

If you use <Invented name> in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.

Preparation of the blister

To help you keep track, 7 week stickers each with the 7 days of the week are provided into the pack. Choose the week sticker that starts with the day you begin taking the tablets (for example, if you start on a Thursday, use the week sticker that starts with “THR”) and place it on the blister card over the words “Place day label here” so that the first day is above the tablet marked “START”. There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows and the consecutive numbers show the order you are to take the pills.

Starting your first pack of <Invented name>

- *If you have not used a hormonal contraceptive in the previous month*
Begin with <Invented name> on the first day of your period. When doing so, you are immediately protected against pregnancy and you do not need to use extra protective measures such as a condom.
- *When changing from a combined pill, vaginal ring or transdermal patch*
You should start <Invented name> on the day after the last active tablet (the last tablet containing the active substances) of your previous pill or on the day of removal of your vaginal ring or transdermal patch (this means no tablet-, ring- or patch-free break). If you follow these instructions, additional contraceptive precautions are not necessary.

You can also start <Invented name> at the latest on the day following the usual tablet-, ring-, patch-free break or placebo interval of your previous contraceptive. In this case, make sure you use an additional barrier method of contraception for the first 7 days of <Invented name> taking.

- *When changing from another progestogen-only pill (POP)*
You may switch any day from other POP and start taking <Invented name> the next day. Additional contraceptive precautions are not necessary.
- *When changing from a progestogen-only- injection or implant or from a progestogen-releasing intrauterine system (IUS)*
You should start <Invented name> the day when the next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive precautions are not necessary.
- *After having a baby*
You can start <Invented name> any day between day 21 to 28 after having your baby. If you start later than day 28 but before the menstruation have returned, you must be sure that you are not pregnant and you must use a barrier method as a condom until you have completed the first 7 days of tablet-taking.

Information for breast-feeding women can be found in section 2 (Pregnancy and breast-feeding).

- *After miscarriage or an abortion*
You should follow the advice of your doctor.

Ask your doctor if you are still not sure when to start.

If you take more <Invented name> than you should

There have been no reports of serious harmful effects from taking too many <Invented name> tablets at one time. Symptoms that may occur are nausea, vomiting and slight vaginal bleeding.

However, in case of overdose, ask your doctor for advice because blood tests should be done.

If you forget to take <Invented name>

You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours. If you are less than 24 hours late in taking any single tablet, take the missed tablet as soon as it is remembered and take the next tablet at the usual time, even if this means taking two tablets at the same time. If you are more than 24 hours late in taking any white active tablet, take the missed tablet as soon as it is remembered, even if this means taking two tablets at the same time and use an additional method of contraception (such as condom) for the next 7 days. Then, continue taking the tablets at your usual time. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.

If you have forgotten a tablet in the **first week** starting the tablets, and you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.

If you forgot to take the tablet **between days 15 - 24 (third or fourth row)**, take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the white active tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different). By skipping the placebo interval, the contraceptive protection is maintained.

The last 4 green tablets in the **4th** row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of <Invented name>. Throw away the forgotten placebo tablet.

What to do in the case of vomiting or severe diarrhea

If you vomit or have severe diarrhea, there is a risk that the active substance in the pill will not be fully absorbed by your body, the situation is almost the same as forgetting a tablet. In these cases, an additional method of contraception may be needed, ask your doctor for advice.

If you vomit or have severe diarrhea within 3-4 hours after taking your white active tablet of <Invented name>, you must take another white tablet from another blister pack as soon as possible. If possible, take it within 24 hours of when you normally take your pill. Additional contraceptive precautions are not necessary. If this is not possible or 24 hours have passed, you should follow the advice given in the section “If you forget to take <Invented name>” above.

If you stop taking <Invented name>

You can stop taking <Invented name> whenever you want. From the day you stop you are no longer protected against pregnancy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, <Invented name> can cause side effects, although not everybody gets them.

Serious undesirable effects associated with the use of <Invented name> are described in the paragraphs 'Breast cancer' and 'Thrombosis' in section 2 'What you need to know before you take <Invented name>'. Please read this section for additional information and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals during the use of <Invented name>. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of <Invented name> is decreased. In general, you need not take any action; just continue to take <Invented name>. If, however, bleeding is heavy or prolonged you should consult your doctor.

If the bleeding is very frequent and irregular, another contraceptive method should be considered. If you don't have vaginal bleeding during the treatment, you may need to do a pregnancy test if you have not taken the tablets in accordance with the instructions in section 3 "How to take <invented name>".

The following side effects have been associated with the use of <Invented name> :

Common: may affect up to 1 in 10 people

- headache
- nausea, abdominal pain
- changes in sexual desire, altered mood
- acne
- breast discomfort, painful periods, bleeding and irregular menstrual periods
- weight gain

Uncommon: may affect up to 1 in 100 people

- anaemia (decreased number of the red blood cells), fatigue (tiredness), fluid retention
- dizziness,
- vomiting, diarrhea, constipation
- vaginal infections
- increased amount of the following, shown in blood tests: potassium, liver enzymes (ALT, AST, GGT), bilirubin, creatine phosphokinase, triglycerides
- appetite changes
- uterine leiomyoma (benign tumor of the uterus)
- depressed mood, depression, anxiety
- absence of menstrual periods, altered menstrual bleeding, pelvic pain, ovarian cysts, vaginal discharge and dryness
- hair loss, increased sweating, itching, rash, seborrhoea (greasy skin), dermatitis (inflammation of the skin)
- elevated blood pressure, hot flushes
- hypersensitivity

Rare: may affect up to 1 in 1,000 people:

- contact lens intolerance
- weight loss
- excessive amount of urine
- breast cyst, breast secretion, abnormal cervical smear, genital itching

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store X

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

White active film-coated tablets:

- The active substance is drospirenone.
Each white active film-coated tablet contains 4 mg of drospirenone.
- The other ingredients are:
Tablet core: microcrystalline cellulose ; lactose; silica, colloidal (E551); magnesium stearate (E470b)
Tablet coat: poly(vinyl alcohol); titanium dioxide (E171); Macrogol; talc (E553b)

Green placebo film-coated tablets:

The green placebo film-coated tablets do not contain active substance.

Tablet core: lactose monohydrate; maize starch; povidone; silica, colloidal (E551); magnesium stearate (E470b)

Tablet coat: hypromellose (E464); triacetin; polysorbate 80 (E433); titanium dioxide (E171); Indigo carmine aluminium lake (E132); yellow iron oxide (E172)

What <Invented name> looks like and contents of the pack

Each blister of <Invented name> contains 24 active film-coated tablets and 4 placebo film-coated tablets.

The active tablet is a round, white tablet with the letters “E” and “D” debossed on opposite sides, with a diameter of 5 mm.

The placebo tablet is a round, green tablet with the letter “E” and the number “4” debossed on opposite sides, with a diameter of 5 mm.

In addition to the carton box, a carton case for the blister is enclosed.

<Invented name> is available in calendar-packs of 1, 3, 6 and 13 blisters, each with 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

Manufacturer

Laboratorios Leon Farma, S.A.
C/ La Vallina, s/n, Polígono Industrial Navatejera,
Villaquilambre 24193 (León), SPAIN

This medicinal product is authorised in the Member States of the EEA under the following names:

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Detailed information on this medicine is available on the website of {MS/Agency}